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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,358	03/04/2002	David Tumey	VAC.702.US	3855

60402 7590 05/13/2008

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/090,358	TUMEY, DAVID	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In view of the pre-appeal conference request filed on January 22, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 5, 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (WO 00/59424 A1) in view of Sasaki et al (U.S. Patent No. 5,039,491).

With respect to **claim 1:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Sasaki teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Sasaki teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this pO_2 measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to include an oxygen sensor for measuring oxygen concentration of the blood conveyed via vacuum flow as taught by Sasaki with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Sasaki thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious.

With respect to **claim 2:** Johnson does not teach a fluid compositional sensing device. Sasaki teaches a fluid compositional sensing device and teaches that such devices are known in the art and include gas chromatograph. Thus the combined teaching of Johnson and Sasaki renders the limitation "the fluid compositional sensing device comprises a gas chromatograph" obvious. The motivation to modify the device of Johnson so as to include a fluid compositional sensing device between the screen means and the vacuum source to measure blood oxygen concentration in the fluid sample conveyed from the body is stated *supra* with respect to claim 1.

With respect to **claim 3:** Johnson does not teach a gas chromatograph. Sasaki teaches a fluid compositional device wherein the sensing device further comprises a photo diode operable in optical
proximity to fluids being drawn from the wound site towards said vacuum source. Sasaki teaches that gas chromatographs are known equivalent devices to the instant optical sensing device having photodiodes, but does not explicitly teach a gas chromatograph that comprises the instant photodiode. The device comprises a cavity chamber for holding a sample that could be replaced by one of ordinary skill in the art with a capillary column as used in gas chromatography. Thus it would be obvious to one of ordinary skill in the art to modify the device of Johnson and Sasaki such that the sensing device is a gas chromatograph comprising a photodiode with a reasonable expectation of success to provide a means of sensing oxygen concentration to indicate a patient's cardiovascular and wound site health. The combined teaching of Johnson and Sasaki renders the limitation "wherein said gas chromatograph further comprises a photo diode operable in optical
proximity to fluids being drawn from the wound site towards said vacuum source" obvious.

With respect to **claim 5:** Johnson teaches a collection canister interposed between said screen means 11 and the vacuum source. Johnson does not teach a fluid compositional sensing device. Sasaki teaches a fluid compositional sensing device. The combined teaching of Johnson and Sasaki thus teaches a collection canister between the screen means and the fluid compositional sensing device. The motivation to combine the teachings of Johnson and Sasaki so as to also comprise a fluid compositional sensing device is stated *supra* with respect to claim 1.

With respect to **claim 6:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14. Johnson teaches a collection canister interposed between said screen means and said vacuum source. (Page 4, lines 18-21)

Johnson does not teach a fluid compositional sensing device interposed between said screen means 11 and said vacuum source. Sasaki teaches an optical oxygen sensor containing an indicator whose change in absorption is a function of concentration of oxygen in a sample, e.g. blood. Sasaki teaches that sensors for determining blood oxygen levels are well-known in the art and can measure blood oxygen by bringing the blood to sensors outside the body, e.g. via vacuum flow such as is taught by Johnson, and teaches that this pO2 measurement is an indicator of cardiovascular function of the patient, which impacts the condition of a wound site and healing time of a wound. Therefore, it would be obvious to one of ordinary skill in the art to

modify the device of Johnson so as to include an oxygen sensor for measuring oxygen concentration of the blood conveyed via vacuum flow as taught by Sasaki with a reasonable expectation of success to provide an indication of a patient's cardiovascular health which impacts conditions at a wound site as well as healing of the wound. The concentration of oxygen in a patient's blood at a wound site is considered herein to be a fluid compositional characteristic of unfiltered wound fluid from the wound bed, as the unfiltered fluid is largely comprised of blood and oxygen is part of the fluid's composition. The combined teaching of Johnson and Sasaki thus renders the limitation "wherein the fluid compositional sensing device senses compositional characteristics of unfiltered wound fluid from the wound bed" obvious.

With regard to the limitation "for detecting infection", the device of the combined teaching of Johnson and Sasaki meets all of the limitations as to a fluid compositional sensing device and thus the instant fluid compositional sensing device is fully capable of detecting infection. With regard to the limitation "said compositional characteristics indicative of said infection within the wound", the instant compositional characteristic, i.e. concentration of oxygen in blood that is within the wound bed fluid, is indicative of infection within the wound inasmuch as insufficient oxygen causes, and is a sign of, infection in a wound bed.

With respect to **claim 10:** The negative pressure therapy device of Johnson further comprises a flexible conduit in the form of material hose 14 for communicating between said screen means 11 and said vacuum source.

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Sasaki et al ('491), as applied to claim 1 above, and further in view of Lewis et al ('440).

With respect to **claim 4:** The fluid compositional sensing device of the combined teaching of Johnson and Sasaki is comprised of a sensor array. Lewis teaches sensor arrays that facilitate detecting more than one condition of, and/or analyte in a fluid, thus facilitating the treatment of a patient or wound site for microorganisms causing infection. Therefore, it would have been obvious to one with ordinary skill in the art to modify the device of the combined teaching of Johnson and Sasaki so as to substitute the sole sensor with a sensor array as taught by Lewis so as to detect microorganisms causing infection at a wound site in the drainage fluids in addition to monitoring cardiovascular health at the wound site.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (‘424) in view of Sasaki et al (‘491), as applied to claim 6 above, and in further view of Scherson et al. ('570).

With respect to **Claim 7:** The combined teaching of Johnson and Sasaki does not teach a sensor embedded in the screen means 11. Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. It would be obvious to one with ordinary skill in the art to embed the sensor taught by the combined teaching of Johnson and Sasaki in the screen means as taught by Scherson to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (‘424) in view of Sasaki et al (‘491) as applied to claim 6 above, and further in view of Fleischmann (U.S. Patent No. 6,398,767).

With respect to **Claim 8:** The combined teaching of Johnson and Sasaki teaches a sensing device and a sealing means but does not teach that said sensing device is disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 ('767, Fig. 1 and Col. 4, lines 62-64). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to modify the sensor and sealing means taught by the combined teaching of Johnson and Sasaki such that the sensor is disposed on the sealing means to detect infections in the atmosphere near the wound area as taught by Fleischmann.

6. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Sasaki et al ('491), as applied to claim 6 above, and further in view of Parker et al (U.S. Patent No. 4,955,391).

With respect to **Claim 9:** The combined teaching of Johnson and Sasaki discloses a canister and a sensing device outside of the canister but does not disclose a sensing device for sensing infections located in the canister. Parker teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col.5, lines 16-21) to monitor parameters of the fluid collected. This provides additional and more accurate means for detecting infection at the wound site as taught by Parker, therefore it would be obvious to one with ordinary skill in the art to provide the invention of the combined teaching of Johnson and Sasaki with the sensing probe of Parker inside of the instant collection canister to provide additional and more accurate means for detecting infection at the wound site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761